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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,970	11/03/2000	Adrian Elmer Leek	1159.2001-000	5060

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/705,970

Applicant(s)

Leek

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, and 14-20 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 12, and 13 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### DETAILED ACTION

Applicants amendment filed June 18, 2003 (Paper Number 9) has been received and entered. Claim 20 has been added, consequently claims 1-20 are pending in the instant application.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 1-4, 7-11, and 14-19 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roy is maintained. Additionally, this rejection is applied to newly added claim 20.

This rejection is withdrawn as applied to claims 5-6 and 12-13 since Roy does not teach or fairly suggest an acid source of hydrogen ions selected from the group consisting of perchloric acid, perbromic acid and nitric acid.

Applicants are asserting that Roy discloses the visualization of *Legionella pneumophila* in paraffin sections using a hexamine silver technique with several sequential steps including: I) bring 3-5  $\mu\text{m}$  paraffin sections to water; II) place in Coplin jar containing 10% potassium dichromate

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for 1 hour at room temperature; III) wash in tap water for 5 minutes; IV) place slides on rack and flood with 3% sodium metabisulfite for 2 minutes; V) wash in running water for 5 minutes; VI) wash well in four changes of distilled water; VII) place in working hexamine solution in a Coplin jar and place in hot-air oven at 56°C.

Applicants assert that this technique describes several “washing” steps with water, metabisulfite, and then again with water, effectively removing the 10% potassium dichromate oxidizer which soaked the material for an hour. Applicants further assert that Roy does not teach treatment with a corrosive reagent such as chromic acid. Applicants finally assert that the Examiner has not provided basis or evidence for considering the silver solution used in Step 7, and prepared with the 7.8 pH boric acid buffer as an “acid source of hydrogen ions.”

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the technique of Roy describes several “washing” steps with water, metabisulfite, and then again with water, effectively removing the 10% potassium dichromate oxidizer which soaked the material for an hour. However, Applicants are respectfully directed to their claims which recite “comprising the steps of...” Washing steps are clearly encompassed within the scope of the claims in view of the transitional phrase of “comprising.” The claims do not recite an amount of chromic acid which must be formed on the biological specimen. Consequently, any residual amount of potassium dichromate which remains in contact with the specimen when the boric acid (step VII) is applied metes the limitations of the claims.

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Second, Applicants assert that Roy does not teach treatment with a corrosive reagent such as chromic acid. However, Applicants are again directed to their own claims. None of the rejected claims recite treatment with "chromic acid." The only limitations are treatment with "an oxidizer that is a precursor of the corrosive reagent and an acid source of hydrogen ions that is other than the corrosive reagent." These limitations have been fully addressed.

Finally, Applicants finally assert that the Examiner has not provided basis or evidence for considering the silver solution used in Step 7, and prepared with the 7.8 pH boric acid buffer as an "acid source of hydrogen ions." However, Applicants are directed to any chemistry textbook. For convenience, a copy of Stryer et al (Biochemistry 1988) is enclosed. On page 41 the ionization equilibrium of a weak acid is given by  $HA \rightleftharpoons H^+ + A^-$ . A weak acid (boric acid) dissociates into a hydrogen ion and a negatively charged ion group, consequently the boric acid solution is a source of "hydrogen ions."

The claims are directed to a method of staining a biological specimen with a histological stain, wherein the specimen is treated by a process that includes treatment with a corrosive reagent, the process comprising the steps of: dispensing onto a biological specimen an oxidizer that is a precursor of the corrosive reagent; and dispensing onto the biological specimen an acid source of hydrogen ions that is other than the corrosive reagent, whereby the oxidizer combines

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with hydrogen ions and the combination of oxidizer and hydrogen ions contacts the biological specimen, thereby treating the biological specimen with the corrosive reagent.

Roy (Stain Technology Vol. 58, No. 4, pp 215-218, 1983) disclose of the visualization of *Legionella pneumophila* in paraffin sections using hexamine silver. Roy further disclose of pretreating the biological sample with potassium dichromate (oxidizer that is a precursor of the corrosive reagent), followed by treatment with Holmes boric acid-borax buffer (acid source of hydrogen ions that is other than the corrosive reagent).

In view that Roy disclose of staining a biological sample with a histological stain comprising dispensing an oxidizer that is a precursor of a corrosive reagent and subsequently dispensing onto the biological specimen an acid source, the disclosure of Roy is deemed to anticipate the claimed invention.

Claims 5-6 and 12-13 are objected to as depending upon a rejected base claim, however claims 5-6 and 12-13 are free of the prior art of record.

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2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal



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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

August 24, 2003